

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing
(day/month/year) **19 MAY 2005**

Applicant's or agent's file reference

CCF-6566PCT

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/US04/12882

International filing date (day/month/year)

27 April 2004 (27.04.2004)

Priority date (day/month/year)

29 April 2003 (29.04.2003)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): C12Q 1/68; C12P 19/34; C07H 21/04 and US Cl.: 435/6, 91.1, 91.2; 536/23/1, 24.3

Applicant

THE CLEVELAND CLINIC FOUNDATION

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US

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Form PCT/ISA/237 (cover sheet) (January 2004)

WRITTEN OPINION OF THE
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International application No.

PCT/US04/12882

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☒ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☒ in written format

☒ in computer readable form

c. time of filing/furnishing

☒ contained in international application as filed.

☒ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US04/12882

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>6-12, 17, 18, 21-30</u>	YES
	Claims <u>1-5, 13-16, 19, 20</u>	NO
Inventive step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-30</u>	NO
Industrial applicability (IA)	Claims <u>1-30</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 1-5, 13-16, 19, and 20 lack novelty under PCT Article 33(2) as being anticipated by Genbank Accession Number U21676.

Genbank Accession Number U21676 teaches the sequence of SEQ ID NO: 1. The complement of this sequence would hybridize to SEQ ID NO: 1 and SEQ ID NO: 2. This sequence is considered 'derived' from SEQ ID NO 1. This sequence comprises the sequences of each of SEQ ID NOS 6-9. This sequence comprises the sequences of the prgH, prgI, prgJ, and prgK genes of Salmonella.

Claims 6-12, 17, 18, and 21-20 lack an inventive step under PCT Article 33(3) as being obvious over Genbank Accession Number U21676 in view of Daum et al.

Genbank Accession Number U21676 teaches the sequence of SEQ ID NO: 1. The complement of this sequence would hybridize to SEQ ID NO: 1 and SEQ ID NO: 2. This sequence is considered 'derived' from SEQ ID NO 1. This sequence comprises the sequences of each of SEQ ID NOS 6-9. This sequence comprises the sequences of the prgH, prgI, prgJ, and prgK genes of Salmonella. Genbank Accession number does not teach primers for the prg gene of Salmonella, fluorescently labeled probes, a method of detecting Salmonella, or a kit comprising a primer and a probe for the prg gene of Salmonella. However Daum et al teaches a method of detecting Salmonella by using PCR primers and fluorescently labeled probes directed to the invA gene of Salmonella (see page 3050, col. 1) in a real time PCR assay (see page 3051, col. 1), for the purpose of detecting Salmonella. Therefore, it would have been obvious to one of ordinary skill in the art to construct primers and fluorescently labeled probes directed to the prg gene as set forth in Genbank Accession Number U21676 for the purpose of detecting Salmonella because Daum et al teach that primers and probes directed to genes from Salmonella can be used to detect Salmonella. It would have also been obvious to the ordinary artisan to package such primers and probes in a kit to make the method of detecting Salmonella as taught by Genbank Accession Number U21676 in view of Daum et al more convenient to perform.